BUMED INSTRUCTION 6270.8

From: Chief, Bureau of Medicine and Surgery
To: Ships and Stations Having Medical Department Personnel

Subj: PROCEDURES FOR OBTAINING HEALTH HAZARD ASSESSMENTS PERTAINING TO OPERATIONAL USE OF HAZARDOUS MATERIALS

Ref: (a) DODINST 6055.5 of January 10, 1989 (NOTAL)
(b) MILSTD 882B (NOTAL)
(c) SECNAVINST 5100.10G
(d) OPNAVINST 5100.24A
(e) OPNAVINST 5100.23B
(f) 29 CFR 19l0.1200 (NOTAL)
(g) OPNAVINST 4110.2

1. Purpose

a. To minimize the health hazards posed by materials or systems under development.

b. To establish formal procedures for obtaining toxicological information on materials in the research and development process being evaluated for introduction into the naval service or for new applications.

c. To assign responsibilities within the Medical Department for performing risk assessments of and publishing appropriate guidance for controlling potential occupational health hazards.

2. Background

a. Research and development (R&D) in the life sciences is directed by reference (a) to assess the effects and impact of specific environmental conditions on personnel health and well-being and to develop criteria to reduce or prevent adverse impact on health status or work performance. Reference (b) specifies the manner in which such R&D must be integrated into the systems development and acquisition process. Implementation within the Department of the Navy is directed in references (c) through (e).

b. Research sponsored by the various commands and program managers often results in development and use of new materials or new applications for existing materials. These materials, or their new uses, may result in significant health hazards for

personnel who encounter them in various operational environments. In many instances, the toxicity data required to evaluate the potential health hazard is inadequate and there are no relevant data for some materials.

c. Information on potential occupational health hazards and required controls is needed by program managers for their use in choosing among alternatives to manage the overall risk while meeting operational requirements. This information also permits early promulgation of appropriate guidelines to control hazards resulting from exposure of personnel to these materials.

3. Definitions

a. New Materials. Includes chemical substances, either in pure form or in mixtures, which are to be used by the Navy for the first time in any capacity. This term also includes the operation or process in which the new material is to be used. This definition specifically excludes medicinals, radionuclides, chemical and biological warfare agents, blood-borne pathogens, and pesticide usage in nonmilitary or unique situations.

(1) New substances, e.g., a compound specially synthesized for a unique application.

(2) Mixtures with different compositions from those currently in use, e.g., a new additive in a hydraulic fluid or a new matrix material for a graphite composite.

(3) Substances already in use by the Navy, but which are being put to a different use, e.g., a boiler water corrosion preventive being used as a propellant or a standard degreasing agent used ashore being considered for use on submarines.

(4) Existing substances which were not previously used in the Navy, e.g., a lubricant used by industry for aircraft engines or a new degreaser to replace Freons.

b. Risk Assessment. As defined by the National Academy of Sciences and adopted by various Federal agencies, is the formal process of using available information to define potential health effects resulting from the exposure of individuals or groups to toxic materials. Risk assessment includes:

(1) Identifying the hazard by determining whether a particular chemical is or is not casually linked to particular health effects (i.e., Is it toxic?).

(2) Quantifying dose-response by determining the relation between the magnitude of exposure and the probability of occurrence of the health effects of concern (i.e., How toxic?).

(3) Evaluating the exposure by determining the extent of human exposure before application of controls (i.e., What exposures are possible?).

(4) Characterizing the risk by describing the nature and magnitude of human risk, including attendant uncertainty (i.e., After combining inherent toxicity and potential for exposure, is there a hazard?).

(5) Recommending controls by describing the nature and degree of controls needed to reduce exposures to an acceptable level (i.e., How can the hazard be minimized?).

(6) Comparing alternatives by summarizing the risks involved and the controls needed for the material of concern and comparing them with those for alternatives to that material (i.e., What are the trade-offs?).

4. Action

a. Activities involved in the research, development, testing, and evaluation (RDT&E) (including "Approval for Service Use") of new materials must:

(1) Forward requests for health hazard risk assessments via the appropriate chain of command to the Commanding Officer, Navy Environmental Health Center (NAVENVIRHLTHCEN), with a copy to MED-242. These requests must be made early in the developmental phase of each program to allow sufficient time for the risk assessment process described above. Provide the following information:

(a) An authoritative technical point of contact.

(b) Details of the material or process under consideration, including the chemical name and formula for each material (and for each component in a mixture or process), and all relevant supplier information. In addition, a current Material Safety Data Sheet conforming to reference (f), as supplied by the manufacturer, should be included.

(c) Description of the intended use of the material, an estimate of the numbers and types of personnel who may be required to work with the material, and an estimate of the quantities likely to be in use and in storage.

(d) If this is a replacement material, include similar information on the material it is to replace, so appropriate comparisons can be provided.

(e) An outline of developmental or introduction milestones for the new material, indicating when the risk assessment must be provided to be considered in the decision process.

(2) Identify availability of funding to support research required to provide toxicological data needed to perform the risk assessment. Such research will be necessary only when the existing toxicological data is insufficient to permit completion of the assessment. The type of studies required will determine how, and how quickly, they can be performed. Funding from the requesting command will be required only if the necessary research cannot otherwise be incorporated into the existing toxicology research program schedule to meet requirements identified in 4a(1)(e).

(3) Immediately notify NAVENVIRHLTHCEN should adverse health effects attributable to exposure to the new material be documented or suspected. Provide a description of circumstances and copies of relevant reports, with a copy of all correspondence to MED-242. Active involvement of local Medical Department occupational health professionals is strongly recommended.

Note: NAVENVIRHLTHCEN will provide interim responses to the requesting command to ensure that obvious hazards are identified early in the process, with recommendations for their surveillance and control. As results from further research become available, additional guidance will be provided. This information is to be used by the requesting command as part of the decision-making process, as prescribed in references (b) and (d). Per reference (e), it must also be incorporated into the command's occupational safety and health program to ensure protection of RDT&E personnel who may be exposed to the new material. Information provided by the final risk assessment must be similarly incorporated and included in the technical publications, standard operating procedures, etc., for the new material as it is introduced into naval service. Contact NAVENVIRHLTHCEN should specific additional guidance or clarification be required.

b. All other commands which are required to comply with the provisions of references (e) and (g) must:

(1) Identify the proposed new material requiring a health hazard risk assessment. If information beyond that available locally is required to complete the risk assessment, the local Bureau of Medicine and Surgery (BUMED) industrial hygienist must refer the request to the NAVENVIRHLTHCEN, where it will be handled as described above. Where the assessment is provided by the supporting BUMED industrial hygienist, an information copy of all health hazard risk assessment reports must be provided to the NAVENVIRHLTHCEN and MED-242.

(2) Use interim guidance and the final risk assessment provided by or through the local BUMED occupational health activity.

(3) Immediately notify the supporting BUMED occupational health activity of any suspected adverse health effects from exposure to the new material.

c. NAVENVIRHLTHCEN is the primary point of contact for assessment of risk due to potential occupational health hazards. NAVENVIRHLTHCEN must:

(1) Undertake a formal review of a new material upon receipt of a request for a health hazard risk assessment. The services and advice of Government agencies as well as private consultants and technical agencies may be used, as appropriate, to obtain data necessary for completion of this evaluation.

(2) Provide a risk assessment to the requesting activity if the information obtained from the administrative toxicological evaluation, combined with the information provided by the requesting activity regarding the probable use conditions and potential exposures, is sufficient to adequately characterize the risk involved.

(3) Provide an interim risk assessment if there is insufficient toxicological information to characterize the risk presented by the new material. This includes recommendations for surveillance and controls based on a reasonable and conservative interpretation and extrapolation of the available information, with the required, but missing, data identified. This interim report must identify the research necessary to provide this data and an estimate of how long such work will take, both with and without supportive funding.

(4) Coordinate with the Naval Medical Research and Development Command (NAVMEDRSCHDEVCOM) in developing each risk assessment for review of toxicological data, determining additional research required, estimating resource availability and project duration, and estimating additional resources required to advance such a project to meet the requesting command's deadlines.

(5) Disseminate information, as appropriate, on the various hazards identified to ensure control of potential exposures and protect the health of personnel working with the new material. This distribution may initially be limited to the requesting command and those occupational health activities supporting their affected activities. On introduction to naval service, this information will be incorporated into Navy Occupational Safety and Health Program guidance by BUMED or Chief of Naval Operations program managers.

(6) Provide information copies of all correspondence and reports to MED-242.

d. The NAVMEDRSCHDEVCOM provides medical R&D expertise to support the Navy's occupational health programs. Much of this expertise resides in the Naval Medical Research Institute Detachment (Toxicology), Wright-Patterson Air Force Base, Ohio which supports the risk assessment process as follows:

(1) Reviews toxicological literature for those requests forwarded by NAVENVIRHLTHCEN to determine if sufficient information is available to characterize the risk presented by the new material. In those cases where there is not enough information, identifies the nature of missing data and experiments, or other methods, necessary to obtain it.

(2) Provides a review and analysis of the above to the NAVENVIRHLTHCEN. If additional research is needed, provides alternative plans for its completion, both within current level of effort funding and identifies additional resources needed to execute it more expeditiously. Considers the requesting command's requirements for timely information by coordinating with them to ensure appropriate prioritization of the effort.

(3) Performs or obtains such research to support Navy requirements within the limitations of available resources.

(4) Maintains liaison with appropriate sources of toxicology expertise (e.g., the U.S. Air Force Armstrong Aerospace Medical Research Laboratory and the National Academy of Sciences/National Research Council's Committee on Toxicology and Advisory Center for Toxicology). Maintains data bases of current toxicology information to prevent duplication of research effort and provides the capability for more rapid assessment and response.

(5) Provides copies of quarterly status reports pertaining to ongoing research efforts and final reports to NAVENVIRHLTHCEN and MED-242.

5. Interservice Coordination. Research reports generated as a result of the above process will be available through the Defense Technical Information Center and the National Academy of Sciences Advisory Center on Toxicology.

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